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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,770	04/28/1999	PIERO DEL SOLDATO	P8907-9002	2174

7590

11/30/2005

ARENT FOR KINTNER PLOTKIN & KAHN  
1050 Connecticut Avenue N W Suite 600  
Washington, DC 20036-5339

EXAMINER
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MITCHELL, GREGORY W

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/147,770	Applicant(s) DEL SOLDATO ET AL.	
	Examiner Gregory W. Mitchell	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 9, 10, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 10 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Office Action is in response to the Remarks and Amendments filed September 01, 2005. Claims 1 and 2 have been cancelled. Claim 27 has been added. Claims 9-10 and 26-27 are pending. Claim 26 is withdrawn from consideration. Claims 9-10 and 27 are examined herein. The cancellation of claims 1 and 2 have overcome the rejections thereto. The rejection to claim 9 is rewritten below and the rejection to claims 10 and 27 are provided below.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Del Soldato et al. (WO 95/30641).

Del Soldato et al. discloses the genus of compounds as anti-inflammatory agents within which the currently claimed compound is a species (pp. 1, 6, 23, 28-29, claim 1). Del Soldato et al. does not specifically disclose the claimed species.

Absent a showing of unexpected results, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the specific compound as instantly claimed because it falls within the scope of the genus disclosed by Del Soldato et al. One would have been motivated to prepare the species claimed

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because of an expectation of success in prepare an agent suitable for anti-inflammatory treatments, as taught by Del Soldato et al.

Claims 10 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Del Soldato et al. as applied to claim 9 above, and further in view of Armour et al. (USPN 5703240).

Del Soldato et al. applies as disclosed above. Del Soldato et al. does not specifically teach the treatment of urinary incontinence.

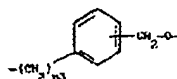
Armour et al. teaches that urinary incontinence is an inflammatory disorder and teaches the use of anti-inflammatory agents for the treatment of urinary incontinence (col. 6, lines 53-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to treat urinary incontinence with the compounds of Del Soldato et al. because (1) Del Soldato et al. teaches the compounds disclosed therein as anti-inflammatory agents; (2) Armour et al. teaches that urinary incontinence is an inflammatory disorder; and (3) Armour et al. teaches the use of anti-inflammatory agents for the treatment of urinary incontinence. Since the Del Soldato et al. and Amour et al. references both teach anti-inflammatory agents, the skilled artisan would have been motivated by an expectation of success to substitute the agents in a treatment of urinary incontinence.

### ***Response to Arguments***

Applicant's arguments filed September 01, 2005 have been fully considered but they are not persuasive.

Applicant argues, "there is simply no teaching or suggestion in Del Soldato *et al.* that would lead one to select the compound of claim 9." This argument is not persuasive. Applicant's attention is directed to pages 23 and 27-28 of Del Soldato *et al.* Del Soldato *et al.* teaches a compound of the formula: A-X<sub>1</sub>-NO<sub>2</sub>. A is specifically taught to be RCOO and R is specifically taught to be the claimed indole structure (see formula IV). X<sub>1</sub> is specifically taught to be -YO- and Y is specifically taught to be:



and  $n_3$  is specifically taught to be 0. Accordingly, it would have been obvious to person of ordinary skill in the art to arrive at the claimed compound. Furthermore, Applicant's claim 9 is directed to an almost identical genus of that taught by Group V, Formula IV in Del Soldato *et al.*

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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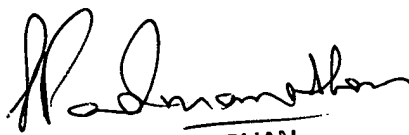
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER